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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,204	12/21/2000	Helena Seppanen	09910-007001	5981

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EXAMINER
DO, PENSEE T

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/646,204	Applicant(s) SEPPANEN ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on April 9, 2003 has been acknowledged and entered. New claims 15-26 have been added. Claims 1-26 are pending.

Withdrawn Rejection(s)

Rejections under 35 USC 112, 2nd paragraph in the previous office action are withdrawn herein.

Rejection under 35 USC 112, 1st paragraph is withdrawn herein.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 7-14, 15, 16, 17, 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins (US 5,705,628) further in view of Tuunanen (US 6,448,092).

Hawkins teaches a method of DNA purification and isolation using magnetic particles. The method comprises of incubating single stranded DNA and magnetic particles in a microtiter plate; Add 100 ul of binding buffer (20% PEG 8000 and 2.5 M NaCl) which corresponds to the surface tension releasing agent in the present invention and mix; magnetically separate the particles and remove the DNA to a new microtiter

plate. The magnetic particles used were the carboxyl coated magnetic microparticles which were 1 um in diameter. (see col. 9, lines 20-30; example 4).

However, Hawkins fails to teach using a magnetic probe to separate the magnetic particles from the mixture and transferring the magnetic particles to the next medium.

Tuunanen teaches a means for separating magnetic particles and transferring them to a second medium/vessel. The means comprises an elongated protective cover that includes a movable rod comprising a rod magnet in the longitudinal direction of the cover. The rod magnet consists of a permanent magnet and a ferromagnetic arm which is its extension. The tip of the magnetic rod is pushed into the liquid mixture, magnetic particles adhere to the tip of the magnetic rod; the magnetic rod is removed from the liquid suspension and transferred to a second vessel/medium, the magnet is lifted up to release the adhered particles into the second medium. The magnetic particles are first concentrated at one spot in the vessel from where they are collected by using a magnetic separation means (see 3, lines 28-60).

It would have been obvious to one of ordinary skills in the art to use the magnetic separation device of Tuunanen to separate bound magnetic particles in the method of Hawkins because Hawkins suggests magnetic separation step and transferring the magnetic particles to a second medium/vessel. By using the magnetic separation rod of Tuunanen, the magnetic separation step of Hawkins' method would be carried out at a faster pace thus would save much time and effort and the particles can be transferred to as many vessels as possible. Regarding the concentration the magnetic particles, it

would have been obvious to one of ordinary skill in the art to adjust such concentration to execute optimum binding between the magnetic particle and the target analyte.

Regarding claim 17, one of ordinary skills in the art would find it obvious to add a STRAs in all the mediums through routine experimentation.

Claims 1-6, 9, 13, 14, 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czerlinski (US 4, 454,234) further in view of Tuunanen (US 6,448,092).

Czerlinski teaches a method for separating magnetic particles. The rabbit anti-BSA antibodies, a given quantity (50 to 100 ul of BSA per 10 ml tube) of BSA-coated magnetic particles are added to a series of tubes. To each tube, a surface tension releasing agent such as a protein of rabbit antiserum diluted in PBS containing 2% (v/v) of normal sheep serum and 0.05% Tween 20 is added. The magnetic particles are collected with a magnet, washed with 4 ml of PBS containing 0.05% Tween 20. They are collected and resuspended a total of three times. (see example 3).

However, Czerlinski fails to teach using a magnetic probe to collect the magnetic particles and transfer them to a second medium.

Tuunanen has been discussed above.

It would have been obvious to one of ordinary skills in the art to use the magnetic separation device of Tuunanen for the magnetic separation step in Czerlinski's method because such as device would accelerate the collection of the magnetic particles and thus would accelerate the speed of the separation step so that results would be obtained at a faster rate since the method of Czerlinski requires that the magnetic

particles must be collected and resuspended a total of three times. Regarding the concentration of the tenside, one of ordinary skills in the art would be able to arrive at a suitable range through routine experimentation.

Response to Arguments

The arguments filed on April 9, 2003 have been considered but not found persuasive.

Regarding the 103(a) rejection by Hawkins in view of Tuunanen, Applicants submit that Hawkins fails to teach the use of STRAs in combination with a magnetic probe. Applicants also submit that an advantage of embodiments of applicants' method is that STRAs prevent particles from adhering to the wall of the reaction vessel. Applicants also indicated that Hawkins teaches that the particles adhere to the wall of the reaction vessel in column 6, lines 3-8 of the Hawkins reference.

In column 6, lines 3-8, Hawkins teaches that the microparticles are then separated from the supernatant, for example by applying a magnetic field to draw down the magnetic particles. There is nowhere in Hawkins that teaches that the particles adhere to the wall of the reaction vessel. Furthermore, the claims of the present invention fail to exclude such limitation of the microparticles being adhered to the wall of the reaction vessel. Moreover, the claims fail to recite that the STRAs prevent particles from adhering to the wall of the reaction vessel. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800

F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is in agreement with the Applicants that Hawkins fails to teach a magnetic probe. However, the missing limitation is relied upon by the secondary reference, Tuunanen. Hawkins teaches a surface tension releasing agent as a binding buffer (20% PEG 8000 and 2.5 M NaCl).

Regarding the 103(a) rejection by Czerlinski in view of Tuunanen, Applicants submit that Czerlinski fails to teach the use of STRAs in combination with a magnetic probe and Tuunanen fails to teach STRAs in a medium.

First of all, the claims fail to recite a combination of STRAs and a magnetic probe. The two components are added separately in the claims. Czerlinski teaches STRAs and Tuunanen teaches a magnetic probe. The motivation to combine the references has been stated in the previous office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christoph L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

Pensee T. Do
Patent Examiner
June 26, 2003